

## **REMARKS**

### **Introduction**

Claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, and 44-45 are pending and claims 46-48, 52-60, and 67-73 have been withdrawn. Applicants expressly reserve the right to pursue the withdrawn and/or cancelled claims in subsequent applications.

New claims 74 and 75 have been added. Support for the new claims can be found, for example, in claim 35 as filed, paragraph [0021], and paragraph [0033]. No new matter has been added.

### **Rejection under 102(b)**

The Examiner has rejected claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, and 44-45 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent Number 4,328,319 issued to Osipow *et al.* (the '319 patent). The Examiner asserts that because the '319 patent "teaches a propellant composition containing a [sic] active ingredient (e.g. drug), a film forming synthetic polymer, vehicle (e.g. water) and other carriers, wherein the composition is made into the final products useful for medicament for external application" the '319 patent anticipates the claims. See Office Action dated February 2, 2007 at p. 3 (the OA). Applicants respectfully disagree.

The '319 patent discloses a "Process for Preparing Propellant Compositions Forming **Foamed Structures** Containing Open and/or Closed Cells." See the '319 patent title (emphasis added). The patentee further states that the compositions disclosed in the patent "are capable of forming **foamed structures**. . . within a few seconds." See, e.g., the '319 patent abstract and col. 4, line 43 (emphasis added). Thus, while many compositions are possible based on the lists of formulary components disclosed in the '319 patent, the '319 patent teaches that the combinations of ingredients form a foamed composition with advantageous speed once volatilized.

In contrast, the claimed invention (as illustrated by at least claim 1) is directed to a sprayable composition for topical application, comprising: from about 0.0001% to about 30% of at least one medicament for systemic or topical availability, at least one film former, at least one vehicle; and at least one component selected from the group at least one permeation enhancer; at least one solubilizer; at least one plasticizer; and at least one water soluble additive; the composition forming a stable, breathable film upon application to a surface. The structure of the composition in the claim, e.g. the components selected for use in the claimed invention including those listed in claim 1, produces a definite and measurable characteristic of the composition, i.e., a stable, breathable film, upon the application to a surface.

This formation of a film using the components of the claimed invention is not taught by the '319 patent. The '319 patent simply does not disclose sprayable compositions for topical application that form a stable, breathable film upon application to a surface. In fact, the '319 patent teaches away from such films by advocating the benefits of a foam structure. Thus, the '319 patent's compositions do not inherently produce a stable breathable film as the Examiner asserts and therefore the '319 patent does not anticipate and/or render the claimed invention obvious.

Further, new claims 74 and 75 are directed to sprayable compositions comprising dimethyl isosorbide. The '319 patent does not disclose the use of dimethyl isosorbide in a propellant composition, much less a propellant composition for topical application that forms a stable, breathable film upon application to a surface. Thus, the '319 patent does not anticipate the claimed invention.

For at least the reasons above, the '319 patent does not anticipate the claimed invention. Therefore, Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. §102(b) and allow the claims.

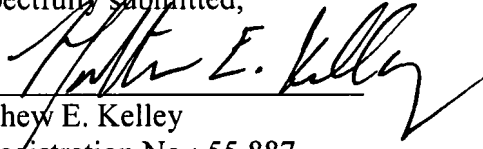
Double Patenting Rejection

Enclosed with this response is a terminal disclaimer which Applicants believe fully responds to and overcomes this rejection. Accordingly, withdrawal of the obviousness-type double patenting rejection is respectfully requested.

In view of the above, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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